K010343

FEB 1 4 2001

510(k) SUMMARY
BMR DENTAL IMPLANT SYSTEM

February 1, 2001

ADMINISTRATIVE INFORMATION

Manufacturer Name: Buck Medical Research
2811 Lemmon Ave., Suite 201
Dallas, TX 75204

Official Contact: Rebecca L. Ellis
Compliance Officer
Buck Medical Research
2811 Lemmon Ave., Suite 201
Dallas, TX 75204
Telephone (214) 522-5780
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DEVICE NAME

Classification Name: Endosseous dental implant

Trade/Proprietary Name: BMR Dental Implant System

Common Name: Dental Implant

ESTABLISHMENT REGISTRATION NUMBER: 1651610

INTENDED USE

The BMR Dental Implant System is intended for surgical placement in the maxillary and/or mandibular arch to support crowns, bridges, or overdentures in edentulous or partially edentulous patients.

DEVICE DESCRIPTION

Design Characteristics

The BMR Dental Implant System is composed of a solid, screw-type cylindrical implant and a solid conical abutment, with associated instruments. The implant is a one-stage non-submerged (transmucosal) design. The implant is available in two diameters and five lengths. Diameters are 4.2 mm (body diameter 3.5 mm) and 3.3 mm (body diameter 2.8 mm). Each is available in lengths of 8 mm, 10 mm, 12 mm 14 mm and 16 mm.

When the implant is surgically placed in bone, the coronal 3 mm portion remains above the crest of the bone. This supracrestal cervical section is flared to a diameter of 4.8 mm and has a polished smooth neck to discourage the accumulation of plaque and calculus and to simplify hygiene. After surgical implantation, the soft tissue is closely adapted around the neck of the implant, leaving the healing screw/tissue contouring screw and the margin of the implant exposed.

Material Composition

Implants and abutments are made from titanium-aluminum-vanadium alloy that meets ASTM designation F-136 (Standard Specification for Wrought Titanium 6Al-4V ELI Alloy for Surgical Implant Applications). In the region that contacts bone, implants are coated with a layer of plasma-sprayed titanium or with a layer of plasma-sprayed hydroxyapatite to facilitate attachment of bone. The use of titanium, titanium alloy, titanium coatings and hydroxyapatite coatings is widespread in commercially distributed, permanently implanted medical devices and the materials are widely considered to be biocompatible.

EQUIVALENCE TO MARKETED PRODUCT

The BMR Dental Implant System is substantially equivalent in indications and design principles to the following predicate devices, each of which has been determined by FDA to be substantially equivalent to pre-amendment devices: ITI Solid Screw Implant and Solid Screw Reduced Diameter Implant, from Institut Straumann, Steri-Oss Threaded HA-Coated Implant, Bio-Vent Implant from Core-Vent and Integral Implant from Calcitek.

Intended Uses

The indications for use for the BMR Dental Implant System and the predicate devices are substantially the same. All are intended for surgical placement in the maxillary and/or mandibular arch to support crowns, bridges, or overdentures in edentulous or partially edentulous patients. The indications for use of the BMR device are not new indications in that they are the same as or are included in those for the predicate devices.

Design and Materials

The design and functional characteristics of the BMR Dental Implant System and the ITI Solid Screw Implant are the same. They are root-form, screw-type, solid body titanium implants intended for support of prosthetic tooth restorations. The ITI implant is CP titanium, Grade 4 and has a TPS coating, while the BMR implant is Ti-6Al-4V and has either a TPS coating or an HA coating. The BMR implant shares the use of Ti-6Al-4V and an HA coating with the Bio-Vent and Integral implants and shares the use of an HA coating on a screw-type implant with the Steri-Oss Threaded HA-Coated Implant.

Mechanical Testing of BMR Dental Implant System

In order to compare the strength of the BMR Dental Implant System with that of the ITI Solid Screw Implant and abutment, static compression bending tests were conducted. The results of testing showed that the BMR Dental Implant System is at least as strong in static bending compression as the ITI Solid Screw Implant and Solid Abutment 6°.

SUMMARY: TABLE OF SUBSTANTIAL EQUIVALENCE

The BMR Dental Implant System is substantially equivalent to the ITI Solid Screw Implant, the Steri-Oss Threaded HA-Coated Implant, the Core-Vent Bio-Vent Implant and the Calcitek Integral Implant in the following respects:

	Subject Device	Predicate Devices			
	BMR Dental Implant System	ITI Solid Screw Implant (K894595, K920928)	Steri-Oss Threaded HA-Coated Implant (K925555, K960886)	Core Vent Bio-Vent Implant (K902968)	Calcitek Integral Implant System (K840750, K946311, K960021)
INTENDED USE					
Surgical placement in the maxillary and/or mandibular arch to support crowns, bridges, or overdentures in edentulous or partially edentulous patients	YES	YES	YES	YES	YES
DESIGN					
Solid body	YES	YES	YES	YES	YES
Threaded	YES	YES	YES	NO	NO

Single stage (transmucosal) design	YES	YES	NO	NO	NO
Smooth transmucosal portion	YES	YES	YES (abutment)	YES (abutment)	YES (abutment)
Morse taper connection between implant and abutment	YES	YES	NO	NO	NO
Diameters, mm	4.2, 3.3	4.1, 3.3	3.8, 6.0		4.0, 3.25
Lengths, mm	8, 10, 12, 14, 16	8, 10, 12, 14, 16	8, 10, 12, 14, 16, 18		
Solid abutment for cemented restorations	YES	YES	YES	YES	YES
MATERIALS					
Implant body and abutment	Ti-6Al-4V	CP Ti	CP Ti		Ti-6Al-4V
Coating	TPS, HA	TPS	TPS, HA	HA	HA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 4 2001

Ms. Rebecca L. Ellis
Compliance Officer
Buck Medical Research
2811 Lemmon Avenue, Suite 201
Dallas, Texas 75204

Re: K010343
Trade Name: BMR Dental Implant System
Regulatory Class: III
Product Code: DZE
Dated: February 1, 2001
Received: February 5, 2001

Dear Ms. Ellis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name: BMR Dental Implant Sysem

Indications for Use:

Intended for surgical placement in the maxillary and/or mandibular arch to support crowns, bridges, or overdentures in edentulous or partially edentulous patients.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K06343

Prescription Use ✓ Over-The-Counter Use_____